

*DMS*

|                  |                 |
|------------------|-----------------|
| Display Date     | <i>11-24-99</i> |
| Publication Date | <i>11-26-99</i> |
| Certifier        | <i>M. Bell</i>  |

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**Immunology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

---

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

*Name of Committee:* Immunology Devices Panel of the Medical Devices Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on December 13, 1999, 9:30 a.m. to 5:30 p.m.

*Location:* Corporate Bldg., conference room 020B, 9200 Corporate Blvd., Rockville, MD.

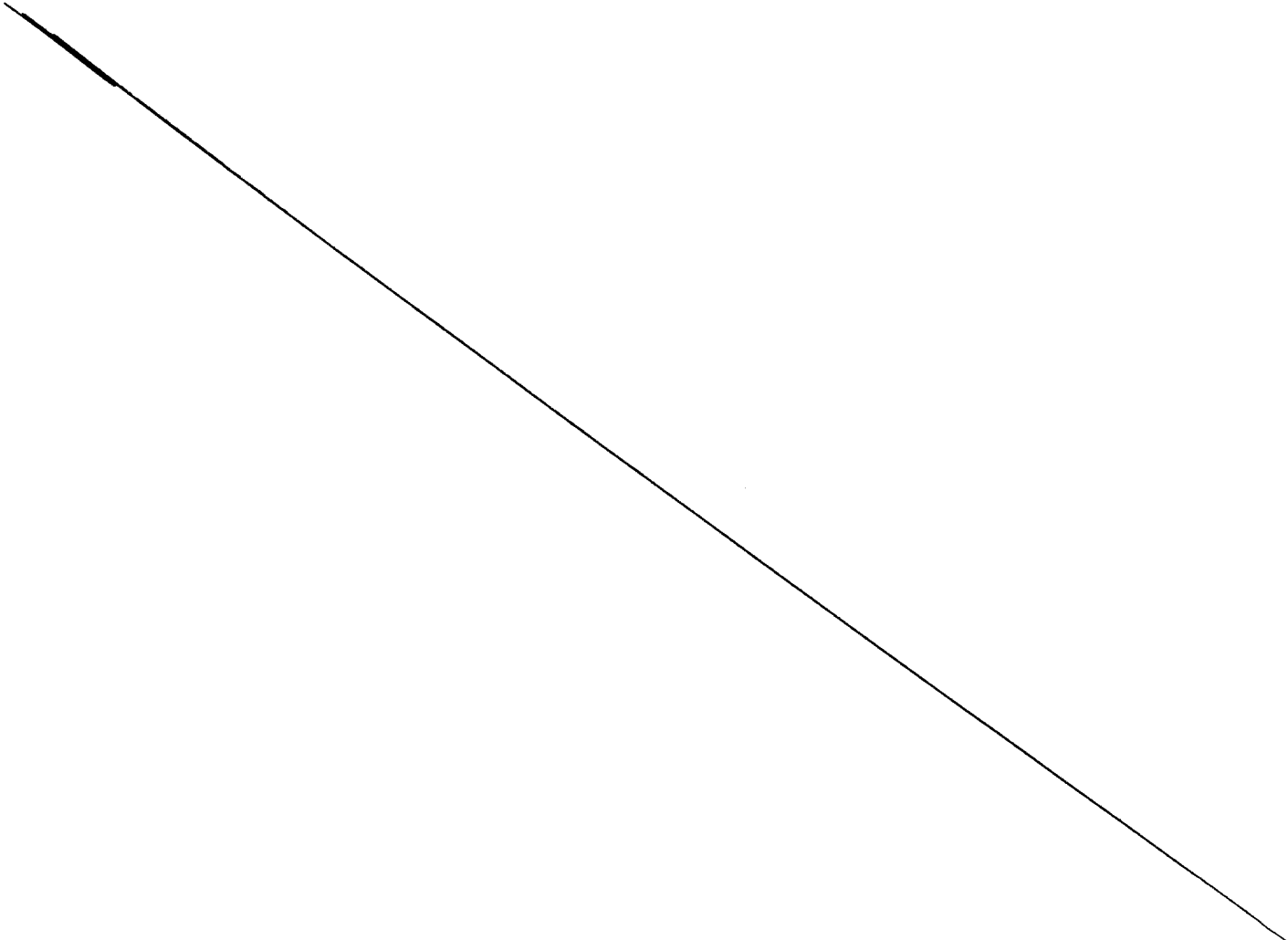
*Contact Person:* Louise E. Magruder, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301-594-1293, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12516. Please call the Information Line for up-to-date information on this meeting.

*Agenda:* The committee will discuss, make recommendations, and vote on a premarket approval application for an enzyme immunoassay to be used as an aid in the diagnosis of patients with transitional cell carcinoma of the urinary tract.

*Procedure:* On December 13, 1999, from 10 a.m. to 5:30 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by December 1, 1999. On December 13, 1999, oral presentations from the public will be scheduled

between approximately 10:45 a.m. and 11:15 a.m. Near the end of the committee deliberations, a 30-minute open public session will be conducted for interested persons to address issues specific to the submission before the committee. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before December 1, 1999, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

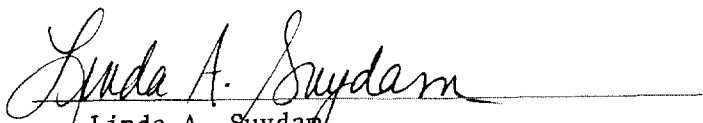
*Closed Committee Deliberations:* On December 13, 1999, from 9:30 a.m. to 10 a.m., the meeting will be closed to permit FDA to present to the committee trade secret and/or confidential commercial information regarding pending and future device submissions (5 U.S.C. 552b(c)(4)). This portion of the meeting will be closed to permit discussion of this information.



Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.

2).

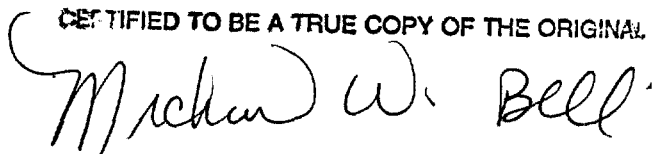
Dated: 11-17-99  
November 17, 1999

  
Linda A. Suydam  
Senior Associate Commissioner

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

**BILLING CODE 4160-01-F**

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

  
Michael W. Bell